DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 14 1997

TO: Manufacturers and Importers of Consumer Electronic Products

SUBJECT: Importation of Radiation-Emitting Electronic Products for Investigation and Evaluation During Design Development

ISSUE

The Consumer Electronics Manufacturers Association has requested that the Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), expand the exemption for consumer products imported for the purpose of test and evaluation during design and production development.

BACKGROUND

Section 536(a) of the Electronic Product Radiation Control provisions of the Federal Food, Drug, and Cosmetic Act (the Radiation Control for Health and Safety Act of 1968) requires that all imported electronic products, for which applicable radiation performance standards exist, shall comply with the standards and shall bear certification of such compliance. Before the products can be permitted to enter the U.S., importers are required to submit with each shipment certain import entry papers through the District Director, U.S. Customs Service, to the appropriate FDA district office.

Exemption from certification of electronic products for the purpose of research, investigations, studies, demonstrations, or training is permitted by Section 538(b) of the Act. Current policy permits FDA district offices to grant such exemptions for individual entries, usually for 180 days, while the products remain in import detention status. Importers must make a written declaration to FDA (Form FDA 2877, "Affirmation C") and execute a bond with the U.S. Customs Service. Liquidation of the Customs bond is attained only through exportation or destruction of the products.

By letters dated May 17, 1982; August 25, 1983; and May 22, 1987, CDRH exempted up to 10 units of the following products from the applicable performance standard when they are intended for investigations: television products, microwave ovens, and laser products that do not exceed the limits of Class I during any conditions of operation, maintenance, or service (hereafter referred to as inherent Class I laser products). The products are not subject to certification requirements or the Customs bonding process under certain conditions. These products are generally used for acceptance testing (FCC, UL, etc.), establishment of production line procedures, and applications evaluation. While they may be fully operational, they may not be the final design and have not received final acceptance testing.

On March 7, 1996, the Consumer Electronics Manufacturers Association (CEMA), a sector of the Electronic Industries Association, requested a change to the industry-wide investigations and evaluation exemption. CEMA asks that the number of units to which the exemption applies be increased to 50 units for TV products and Class I laser products and to 200 units for CD-ROM and new DVD (digital versatile disc) laser products, to reduce unnecessary costs to manufacturers in both time and money. Increase to 50 units will accommodate the industry need for establishing production processes. Increase to 200 units for CD-ROMs and DVDs will accommodate the need for software evaluation and development. Because there will be no commercial distribution of the products, the change is expected to reduce the tracking and paperwork burden on industry, FDA, and U.S. Customs, without impact on public health.

EXEMPTION

Under the authority of Section 538(b) of the Act, exemption from certification to the applicable radiation performance standards and the execution of a Customs bond is granted for consumer electronic products imported into the U.S. for investigations and evaluation during the design and production development phase with the following conditions:

1. The quantity of products in any single import entry of television products, microwave ovens, and inherent Class I laser products can not exceed 50 units; except other laser products requiring software to operate, such as CD-ROMs and DVDs, are limited to 200 units.

2. Each product and its shipping carton must bear a label stating: "TESTING/EVALUATION ELECTRONIC PRODUCT - NOT TO BE SOLD IN THE UNITED STATES. THIS PRODUCT HAS NOT BEEN TESTED FOR COMPLIANCE WITH THE APPLICABLE U.S. RADIATION PERFORMANCE STANDARD."

3. The importer or consignee must establish written procedures for maintaining control and final disposition of the products.

4. Form FDA 2877 (Declaration For Electronic Products Subject to Radiation Performance Standards), or the equivalent electronic filing, must be submitted to the FDA district office before the shipment arrives. Until the Form 2877 is revised to provide an affirmation for this exemption, mark Affirmation A and write: "These products meet the CDRH Exemption For Product Development and will not be commercially distributed at any time."

5. Shipments in excess of the quantities specified in item 1, or otherwise not meeting the conditions above, shall be placed in import detention status.

Movement of uncertified products in U.S. commerce is a violation of Section 538(a)(1) of the Act. Violations will result in voiding this exemption for the responsible parties and are subject to civil penalties not to exceed $1000 per violation and $300,000 maximum. Providing false information to the U.S. government is a violation of the U.S. Code, Title 18, and subject to criminal prosecution.

This exemption supersedes the previous exemptions dated May 17, 1982; August 25, 1983; and May 22, 1987.

Any questions regarding this exemption or any imports procedure should be directed to the imports officer at the FDA district office nearest the port of entry.

Sincerely yours,

Lillian J. Gill

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Director
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